

**REMARKS**

These remarks are in response to the Final Office Action mailed June 21, 2006. Claims 1-21 are pending in the application. Claims 1, 2, and 11-21 are withdrawn from consideration as being drawn to non-elected matter. Claims 2 and 13 have been canceled without prejudice to Applicants' right to prosecute the canceled claims in any continuation, continuation-in-part, divisional or other application. Claims 3-10 have been indicated as allowable. Claim 22 is rejected. Claim 22 has been amended herein to further clarify the invention. Claims 23 and 24 have been added as dependent claims from claim 22. The amendments are fully supported by the specification as set forth below and in paragraphs [0037]-[0039]. No new matter is believed to have been introduced. In addition, the amendments and new claims do not introduce new matter requiring a further search as the Examiner has already searched the scope of claim 22, upon which claims 23 and 24 depend.

**REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claim 22 stands rejected under 35 U.S.C. §112, first paragraph, because the specification while being enabling for a method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with an inhibiting effective amount of a peptide consisting of an amino acid sequence as set forth in SEQ ID NO:2 from about amino acid 31 to 131, allegedly does not reasonably provide enablement for a method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with any peptide consisting essentially of an amino acid sequence as set forth in SEQ ID NO:2 from about amino acid 31 to 131. The specification allegedly does not enable any person skilled in the art with which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with this claim. Applicants respectfully traverse this rejection.

In particular, it appears the Examiner is construing "consisting essentially of" as being open ended and cites to the MPEP §2111.03. Applicants respectfully submit that the Examiner misreads the cited cases and application of "consisting essentially of". MPEP §2111.03 describes the scope of "consisting essentially of" as

limiting the scope of a claim to the specified materials or step "and those that do not materially affect the basic and novel characteristic(s) of the claimed invention. *In re Herz*, 537 F. 2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). MPEP §2111.03 goes on to state, "For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims or what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising'." It appears the Examiner is construing the scope of "consisting essentially of" for purposes of searching as encompassing "comprising," even though the specification identifies the novelty of the claimed invention. As identified in MPEP §2111.03, the claims for purposes of searching "consisting essentially of" are to be construed with reference to the specification.

In this regard, Applicants submit that the specification clearly sets forth the novel characteristics such that the scope of the claims can be properly determined based upon the specification and the transitional phrase "consisting essentially of". For example, the specification states at the following paragraphs:

[0020] The antimicrobial activity of hCAP18/LL-37 has been attributed to the action of the C-terminal peptide (in humans known as LL-37) after proteolytic processing of the precursor protein (in humans known as hCAP18/LL-37) to "remove" the N-terminal cathelin-like domain.

[0023] Cathelicidin proteins are composed of two distinct domains: an N-terminal "cathelin-like" or "prosequence" domain and the C-terminal domain of the mature AMP. . . . The term "cathelin-like" derives from the similarity of the N-terminal sequence with that of cathelin, a 12 kDa protein isolated from porcine neutrophils that shares similarity with the cystatin superfamily of cysteine protease inhibitors.

[0027]. . . The cathelin-like peptide comprises from about amino acid  $x_2$  (wherein  $x_2$  is between and inclusive of amino acids 29-31 of SEQ ID NO:2) to about amino acid  $x_3$  (wherein  $x_3$  is between and inclusive of amino acids 128-131 of SEQ ID NO:2). For example, the cathelin-like domain may comprise from about amino acid 31 to about amino acid number 131 of SEQ ID NO:2.

[0030]. . . The disclosure further demonstrates that the human cathelin-like domain acts as cysteine proteinase inhibitor and that it exhibits antibacterial activity against pathogens including *E. coli* and methicillin-resistant

*Staphylococcus aureus (MRSA). This antimicrobial activity is distinct from that of the LL-37 peptide.*

[0033] As used herein, the term "cationic cathelin-like peptide" refers to a chain of amino acids that is about 96 to about 104 amino acids in length and comprises a sequence as set forth in SEQ ID NO:3 or the N-terminal cathelin-like domain of SEQ ID NO:2. . . .

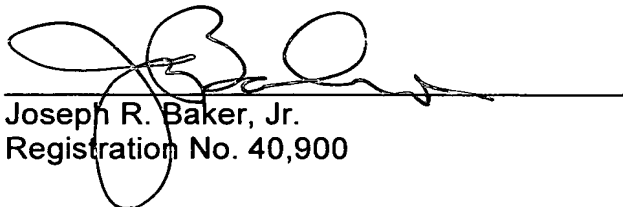
Accordingly, the specification indicates what the basic and novel characteristics actually are for interpreting "consisting essentially of". From the specification it is clear that the cathelin-like domain/peptide is novel and functional. In addition, the specification defines the cathelin-like domain/peptide sufficiently that one of skill in the art would recognize the scope of "consisting essentially of" in the claims including functional variants (see, e.g., paragraphs [0037-0039]).

For the reasons set forth above, it is believed that this case is in condition for allowance. Applicants accordingly request that this Amendment be entered and that the rejections under 35 U.S.C. §112 be carefully reconsidered. In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that the prosecution of this application may be expedited.

Respectfully submitted,

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